

**Notice of Allowability**

Application No.

10/627,499

Examiner

Xiaozhen Xie

Applicant(s)

KINK ET AL.

Art Unit

1646

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--**

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 11/17/2006.
2. ☒ The allowed claim(s) is/are 59-65, renumbered as 1-7, respectively.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some\* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL..

**Attachment(s)**

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO/SB/08),  
Paper No./Mail Date 20061117
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),  
Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

*Eileen B. O'Hara*  
EILEEN B. O'HARA  
PRIMARY EXAMINER

## **DETAILED ACTION**

### ***Status of Application, Amendments, And/Or Claims***

The Information Disclosure Statement (IDS) filed 17 November 2006 has been entered. An interview was conducted on 9 April 2007 and Examiner indicated that the finality of the previous Office Action was withdrawn due to potential new grounds of art rejection. However, upon further review, it has been decided that the application is in condition for allowance.

Claims 1-58 and 67 have been cancelled. Claims 66 and 68 have been rejected. Applicant has provided authorization for canceling claims 66 and 68 in a telephone interview with Attorney Jason R. Bond. Claims 59-65 are in condition for allowance.

### ***Reasons for Allowance***

The following is an examiner's statement of reasons for allowance:

The instant claims are directed to a method of reducing symptoms of inflammatory bowel disease, comprising administering to a human patient afflicted with the disease a therapeutic formulation comprising antibodies directed against  $\text{TNF}\alpha$  which is purified from an avian egg yolk, such as a chicken egg yolk, wherein the formulation is administered to the lumen of the intestine of the patient, such as rectally, wherein said human is a child. Using  $\text{TNF}\alpha$  antibodies for treating inflammatory diseases, e.g., Crohn's disease (CD), ulcerative colitis (UC), has been described in prior art (e.g., Le et al., US 5,698,195, issued on 16 December 1997; Aggarwal et al., US 5,795,967, issued on 18 August 1998; Anagnostopulos et al., WO 92/07585,

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International Publication Date on 14 May 10992; Hawkey C. J., in Inflammatory Bowel Diseases, R. N. Allan (eds), New York, Churchill Livingstone, 1997, pp. 521-534).

However, the method of administration taught in prior art is *via* parenteral administration, i.e., intravenous, subcutaneous, intramuscular injection. Prior art teaches that anti-TNF $\alpha$  antibodies (polyclonal, monoclonal, humanized antibodies) are unlikely to be administered orally because proteins are digested when administered orally. The instant invention contemplates administering TNF $\alpha$  antibodies purified from an avian egg yolk to the lumen of the intestine of a patient afflicted with the disease, (e.g., orally, rectally). Applicant discloses that elevated TNF and other mediators are primarily limited to the intestine mucosa and lamina propria, and the concentration of TNF can be detected in the stools of afflicted children while serum concentration remains low. Applicant discloses that avian egg yolk produced-TNF $\alpha$  antibodies are particularly advantageous for oral preparation of therapeutic antibodies because they can be generated in large quantities and formulated to resist gastric digestion. At the time the invention was filed, Applicant had shown success of oral delivery of avian anti-TNF $\alpha$  antibodies in treating CD in animal models (Worledge et al., 2000, Dig. Dis. and Sci., 45(12):2298-2305). Therefore, the instant invention is novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Xiaozhen Xie, Ph. D.  
April 12, 2007



EILEEN B. O'HARA  
PRIMARY EXAMINER